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FIRST NAMED INVENTOR APPLICATION NO. FILING DATE ATTORNEY DOCKET NO. CONFIRMATION NO. 10/008,140 10/18/2001 08841.105021 2922 Lieven Stuyver 04/27/2004 **EXAMINER** Sherry M. Knowles, Esq. JOHANNSEN, DIANA B KING & SPALDING ART UNIT PAPER NUMBER 45th Floor

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DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Application/Control Number: 10/008,140

Art Unit: 1634

Notice of Non-Responsive Amendment

- 1. Amended claim 23 and claims dependent therefrom, as well as newly submitted claims 56-63, are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons.
- Regarding claim 23 as amended (as well as claims dependent therefrom), a) it is noted that the claim has been amended such that it is now drawn to a method in which detectable signals produced during amplification of host mitochondrial/host nuclear nucleic acids are compared; such methods are classified in, e.g., class 435, subclass 91.2. In contrast, claim 23 as originally filed was drawn to a method in which first and second primers and/or probes were provided, and in which said primers and/or probes produced signals upon the occurrence of transcription of host mitochondrial and/or host nuclear nucleic acid; such methods are classified in, e.g., class 435, subclass 6. While the original claims were drawn to methods in which gene transcription/expression was assayed, the claims as amended are instead drawn to methods of amplifying and detecting mitochondrial and nuclear nucleic acids (rather than transcripts). Such methods are separately classified because they require the performance of different process steps, and further, examination of the distinct invention of claim 23 as amended would require a separate search that is not coextensive with that performed during examination of original claim 23.
- b) Regarding new claims 56-63, the claims are drawn to kits comprising various combinations of primers of several different particular sequences, as well as dyes. This invention is classified, for example, in class 536, subclass 24.33, and class

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435, subclass 810. No claims directed to such an invention were previously presented or examined; nor did the claims previously examined in the application recite any of the primers of the instant claims. Claims 56-63 are separately classified from the invention under examination in the instant application, and further, examination of the inventions of claims 56-63 (e.g., of the different primer combinations of the claims) would require different searches of, e.g., particular nucleotide sequences and combinations thereof, which search is separate from and not coextensive with that which was required for the elected invention.

- 2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because these inventions require different text searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner, and the various inventions now presented for examination would have been properly restricted from the invention already examined had they originally been presented together.
- 3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23-29, and 32-63 are withdrawn from consideration as being directed to a non-elected invention. The amendment filed on October 27, 2003, canceling all claims drawn to the elected invention and presenting only claims drawn to non-elected inventions is non-responsive and has not been entered. See 37 CFR 1.142(b) and MPEP § 821.03.

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- 4. Since the above-mentioned amendment appears to be a bona fide attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have guestions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Diana B. Johannsen

Patent Examiner

April 23, 2004